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Briefing Report to the Chairman,
United States Bipartisan Commission
on Comprehensive Health Care

February 1990

QUALITY ASSURANCE

A Comprehensive,
National Strategy for
Health Care Is Needed

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Program Evaluation and
Methodology Division

B-237200

February 21, 1990

The Honorable John D. Rockefeller IV
Chairman, The Pepper Commission
United States Bipartisan Commission on
Comprehensive Health Care

Dear Mr. Chairman:

In response to your request of August 11, 1989, we have examined the issues that would need to be addressed in ensuring the quality of health care under any plan to expand health care coverage for the uninsured. We have assumed that the current system of multiple public and private purchasers of health care will remain in place for at least the immediate future. In addition, we have examined the adequacy of the knowledge base for structuring such quality assurance activities. However, because we believe that most of the quality assurance issues that would need to be addressed are generic, much of this report does not distinguish between quality assurance for the uninsured and for the general population.

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This briefing report presents the results of our work as discussed with your staff on January 23, 1990. We begin by noting that quality is multidimensional and that we have focused our attention on the appropriateness of care and the technical and clinical aspects of quality. We also note that health care system design has important implications for quality, and we briefly describe the various levels at which quality assurance activities are currently conducted. We conclude that there is a considerable body of knowledge about, and experience with, the organization and conduct of quality assessment and assurance activities and a growing interest in improving and expanding these activities among many of the participants, including the medical community, consumers, employers, and purchasers of care.

In keeping with this growing interest, we suggest that a comprehensive, national strategy for assessing and assuring the quality of health care is needed. We see at least four elements as essential to a comprehensive national strategy: (1) national practice guidelines and standards of care; (2) enhanced data to support quality assurance activities; (3) improved approaches to quality assessment and assurance at the local level; and (4) a national focus for developing, implementing, and monitoring a national system. The reasons we see for needing a comprehensive

national approach and a brief discussion of each of its elements are contained in section 2 of this report.

Our conclusions are based primarily on the studies of health care quality assessment and assurance in a number of settings spanning the public and private sectors that we have conducted over the past few years. We have also incorporated concepts and information on quality assurance contained in published sources, including the Institute of Medicine's report entitled Controlling Costs and Changing Patient Care? and the Office of Technology Assessment's report entitled The Quality of Medical Care: Information for Consumers. Finally, we convened a meeting of experts in November 1989 for the explicit purpose of exploring these issues and have had them review a draft of this report. (See appendix I.) We have not conducted a comprehensive review and analysis of existing quality assurance programs. Any references in this report to specific quality assurance programs are examples used to illustrate particular points and do not necessarily represent the "best" programs available.

Our work was performed in accordance with generally accepted government auditing standards. We have incorporated the comments of our experts but have not requested comments from any federal agency, since none is evaluated in this work. Unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from its date. We will then make copies available to others upon request. If you have any questions or would like additional information, please call me at (202) 275-1854 or Mr. Robert York, Acting Director of Program Evaluation in Human Services Areas, at (202) 275-5885. Other major contributors to this report are listed in appendix II.

Sincerely yours,



Eleanor Chelimsky
Assistant Comptroller General

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Abbreviations

GAO	General Accounting Office
PRO	Peer Review Organization

Quality, Quality Assurance, and the Health Care System

In this section, we begin with an overview of the concept of health care quality and how we use it in this report. We draw a distinction between quality assessment and quality assurance, which is important for our discussion of the need for a national, comprehensive quality assurance strategy in section 2. We note some instances in which the design and operation of the health care system itself can influence quality quite independently of any formal mechanism for reviewing the quality of care. Finally, we briefly describe the different levels in the health care system at which quality issues may be addressed.

Quality Is Multidimensional

The quality of care is a multidimensional concept that defies simple definition. Quality encompasses many aspects of care and means different things to different people. Patients, health care providers, and purchasers may have different notions about what constitutes high-quality care.

- To patients, "getting better" (that is, the outcome of care) is probably the primary concern. In addition, having access to care that is affordable, conveniently available, and provided in a manner that respects their concerns and preferences is important. The responsiveness of the delivery system may also be important—for example, meeting patients' individual needs for emergency care, coordinating services, and making appropriate referrals.
- Health care providers may emphasize the decisionmaking process that underlies diagnosis and treatment, the clinical content of care, and the technical skill with which it is rendered.
- Purchasers may place greater weight on questions of cost-effectiveness, including the need for individual diagnostic and therapeutic services, the appropriateness of the setting in which care is delivered, and the frequency, timing, and duration of services.

All these views of quality are legitimate and important. However, our primary focus is on the appropriateness of medical services and their clinical and technical quality. This implies a concern for such issues as whether necessary care was provided, whether the outcome was acceptable, whether unnecessary services were provided, and whether the location of care (that is, hospital, nursing home, home, ambulatory setting, and so on) was consistent with the patient's needs.

There are important reasons for this focus. First, and perhaps most important, providing appropriate medical care that is effective is the common denominator of the preferences of all three groups. Second, providing improved access to inappropriate care or poor-quality care is not

likely to result in improved health outcomes. Third, currently available strategies for assessing and assuring quality are targeted especially to the appropriateness of care and to technical aspects of quality. As a result, focusing attention in these areas offers the greatest potential for near-term improvements in quality.

Quality Assessment Should Be Distinguished From Quality Assurance

It is important to distinguish between quality assessment and quality assurance. Quality assessment involves the use of measures of quality, based on either explicit or implicit criteria, to assess the structure, process, and outcome of care and to monitor levels of quality over time. Quality assurance goes beyond the simple assessment of quality to include its improvement. This requires identifying and confirming problems in the quality of medical care, planning interventions to lessen or eliminate the problems, monitoring the effectiveness of the interventions, and instituting additional changes and monitoring where warranted.

Quality assessment is a prerequisite to quality assurance. It can be performed by an external assessor, assuming that the information necessary to assess the medical care is available and that criteria exist for specifying the constituents of high quality. Under these conditions, potential problems with the quality of care can be easily identified.

Successful quality assurance is more difficult, since it involves either preventing poor-quality care from occurring or improving levels of quality, which frequently requires behavior change on the part of health care providers. One example of an approach to preventing poor-quality care is to require external approval of health care interventions before the care is provided. This approach works because care that is not approved is unlikely to be reimbursed and this lessens the likelihood that the presumably inappropriate care will be provided.

But such approaches apply to individual services or procedures patient by patient. They do little to encourage providers to change their behavior or to create an environment for improving general levels of quality over time. Accomplishing the latter is generally assumed to require the commitment and involvement of the health care providers whose care is under review. This involvement is particularly important in the "gray" areas of medicine where there may be uncertainty about what the proper course of treatment is and considerable variation among physicians in how they currently care for patients. If physicians and other

health care providers collectively examine information on current practice patterns and determine the reasons for variation and the preferred methods of treatment, the potential payoff in terms of improving overall levels of quality is considerable.

Quality assurance systems typically concentrate on quality assessment and on the identification of the relatively small number of providers whose care is obviously unacceptable. They do comparatively little in attempting to directly improve the overall levels of quality provided by the majority of health professionals. This is more difficult to accomplish, particularly if imposed on health professionals from the outside. If we think of the performance of health care providers in terms of the bell-shaped curve of a normal distribution, the challenge is to devise a quality assurance strategy that not only deals appropriately with the outliers but also assists in moving the entire distribution to a higher level of quality.

Health Care System Design Influences Quality

Quality is potentially influenced by almost every aspect of the design and performance of the health care system. While it is important to have effective systems for monitoring the quality of care after it is provided, it is equally, if not more, important to try to "build it in" up front. In particular, having access to needed services is a prerequisite for receiving services of high quality. For example, if a program

- does not cover a range of preventive, acute, and continuing services that are needed by the eligible population, then individuals may not have access to needed services;
- does not allow adequate reimbursement for certain services, then providers may decline to provide those services and access to care may be impeded;
- has inefficient or burdensome administrative requirements, then providers may choose not to accept patients covered by that program, again curtailing access;
- has limited ability to direct patients to high-quality providers or to foster quality among participating providers, then the care patients receive may be of varying levels of quality.

Systemic issues also affect quality. For example, an oversupply of a particular medical specialty or hospital service in a given area may mean that no provider serves enough patients to develop and maintain necessary skills or that unnecessary services will be provided in order to maintain patient volume. Malpractice is another example. The fear of

malpractice suits may cause some providers to give care that is not needed and, in the case of invasive procedures, put the patient at unnecessary risk. High malpractice premiums and judgments may contribute to increasing health care costs, thereby lessening access to care for some people. While a detailed consideration of these issues is beyond the scope of this report, they are nonetheless important and deserve attention. Some of them are being addressed in other studies under way at GAO.

Quality Assessment and Assurance Occur at Many Levels

Throughout the nation, many existing programs of quality assessment and assurance can provide a foundation for the review of quality under new initiatives to expand health care coverage. Purchasers of health care have instituted quality assessment and assurance programs to fulfill their fiduciary or public accountability responsibilities to persons whose care they finance. The Health Care Financing Administration conducts quality assurance activities for Medicare through its system of Peer Review Organizations (PROs) for primarily hospital and some ambulatory care and through carriers and intermediaries for nonhospital care. The Health Care Financing Administration's annual release of hospital mortality statistics and information on the quality of care in nursing homes are additional examples of such activities. State Medicaid agencies have requirements to monitor the use of services by Medicaid recipients; this is accomplished in a number of states through contracts with the PROs. Finally, private insurers also have quality assessment and assurance systems that resemble those of Medicare and Medicaid but also vary, depending on the needs of the health care purchaser and reimbursement methods.

The approaches above to quality assurance are sometimes referred to as "external," "regulatory," or "administrative" quality assurance. Their intent is to make sure that the care for which payment is made is appropriate. There is an emphasis on utilization control, although outcomes and other aspects of quality may also be examined, as exemplified by the PRO's use of generic quality screens. The reviews of care are frequently conducted far from the site of care. While there may be some interaction with, and feedback of information to, the providers whose care is being reviewed, the providers themselves are not deeply involved in the process of review. Quality assessment is a more dominant feature of these activities than quality assurance.

The quality of care may also be monitored and influenced at the community level or within a health service area. In addition to the review of

the quality or appropriateness of individual services, quality-relevant issues to be addressed include whether there is an appropriate supply and distribution of health care providers of various types and specialties, whether the volume of services provided by individual providers is high enough to maintain acceptable skill levels, and whether effective mechanisms exist to refer patients to needed services, coordinate those services, and place patients at appropriate levels of care. Because of the highly individualized and dispersed nature of health care, many communities lack a structure for making such judgments and exerting leverage on the health care system. However, there are some voluntary efforts to develop community-wide programs. For example, a plan called Cleveland Health Quality Choice, involving the physician, hospital, and business communities, is committed to evaluating the quality of hospital care in the Cleveland area and directing patients to hospitals providing high-quality care. In Minnesota, the Twin Cities Voluntary Health Care Information Project is reviewing quality indicators for hospitals and health plans in hopes of assisting health care purchasers and providers in making purchasing decisions.

Finally, many health care institutions, as well as individual providers, have voluntarily implemented their own internal quality assurance programs, reflecting a commitment to what has been termed "continuous quality improvement." The Harvard Community Health Plan, for example, has developed and implemented a program to measure quality of care that generates information to be used by clinicians and managers for identifying the reasons for problems and instituting changes intended to improve the quality of care. The Park Nicollet Medical Center in Minneapolis has developed an internal system for monitoring health care outcomes, concentrating initially on patients with heart disease and arthritis. Individual hospitals have instituted similar approaches. Small physician practices, lacking an organizational structure and patient volume to warrant a structured, statistical reporting system, have nevertheless implemented ongoing quality reviews through such approaches as bringing in outside peer reviewers to review their case records and to give them feedback on strengths and areas for improvement. The key to these initiatives is that they are voluntarily and internally generated. The health professionals involved are committed to determining the levels of quality of the care they currently provide, identifying opportunities for improvement, and seeing that improvement occurs and quality is ensured.

Some health care analysts have viewed these various levels of quality assessment and assurance as being either redundant or in opposition to

one another, if not actually working at cross purposes. This is particularly true when the paperwork and administrative requirements of external reviews are burdensome and are not viewed as adequately addressing and resolving true quality problems. However, there are examples of situations in which the various levels have been complementary and mutually reinforcing. And, in some instances, the presence of external review has provided an impetus for initiating internal reviews.

We believe that the important thing to note is the considerable body of knowledge about, and experience with, organizing and conducting quality assessment and assurance activities. There also appears to be growing interest in improving and expanding these activities among many of the participants, including the medical community, consumers, employers, and purchasers of care. While this interest could be manifested in an increased regulatory burden, it could also be developed into a more balanced system of quality assurance that uses external entities to monitor overall levels of quality of care and identify potential problems. More direct interventions could be limited to instances in which serious quality problems are confirmed or when a provider's internal quality assurance mechanisms appear to have failed. The hope that a better balance between internal and external quality assurance can be achieved has shaped many of the observations and suggestions in the next section.

A Comprehensive, National Quality Assurance Strategy Is Needed

We believe that a comprehensive, national approach to quality assurance is required. By comprehensive and national we mean that, regardless of the source of payment or individual patients' circumstances, similar individuals with similar medical needs should be assured of receiving the same type of appropriate, high-quality care. This implies that similar requirements for quality assessment and assurance should apply across all purchasers, providers, and health care settings. We begin this section by discussing why we believe that a comprehensive national strategy is needed. We then discuss the desirability of blending into a balanced national system an external quality assurance capability together with a community of health care providers who are committed to continuing self-assessment and improvement.

Finally, we describe the essential elements of a comprehensive national strategy and discuss what is needed to move from the current quality assurance environment toward a comprehensive national strategy. The elements that we see as essential are national practice guidelines and standards of care, enhanced data to support quality assurance activities, improved approaches to quality assessment and assurance at the local level, and a national focus for developing, implementing, and monitoring a national system. Although components of each element exist today, it will take time and effort to develop, implement, and refine the type of comprehensive national strategy we envision. But much of the groundwork has already been laid.

Reasons for a Comprehensive National Strategy

We believe that a comprehensive national strategy is important for several reasons. The first is equity: the intent and stringency of quality assurance requirements should not depend on whether the care is financed by Medicare, Medicaid, expanded employer mandates, or some other arrangement for coverage expansion. However, some variation or flexibility in the specific review approaches is probably warranted to account for differences in covered populations, types of services, or reimbursement methods. For example, the focus of review for a population consisting primarily of mothers and children might be different than that for predominantly middle-aged employed persons. Similarly, assessment methods for persons enrolled in a prepaid group practice might concentrate on potential quality problems associated with underuse of services, while those for persons whose care is reimbursed on a fee-for-service basis might concentrate on the potential for overuse. Nevertheless, the overall intent and stringency of review requirements should be similar.

Second, health considerations dictate a comprehensive approach. Meeting the health care needs of individuals frequently requires providing care in a variety of settings (that is, hospitals, physicians' offices, nursing homes, home health agencies, and so on) over an extended period of time. What occurs in one setting or at one time is often influenced by what occurred in a different setting at a different point in time. Thus, it is important to be able to track the contents, appropriateness, and outcomes of care for an episode of illness, regardless of when and where the care was provided or who paid for it. Most current quality assurance systems do not have this capability.

Finally, certain operational aspects of quality assessment require a comprehensive approach. For example, many judgments about quality are based on patterns of care rather than isolated instances. If one were to examine only the patients cared for by a single provider and who had a common insurer or payment source, the number of patients might not be sufficient to provide an accurate assessment of that provider's performance. However, by combining information on care provided by a single provider regardless of the source of payment, more stable profiles of care can be generated, permitting more definitive quality assessments.

The Need for Balance

In general, our view is that the quality of care emerges most effectively from an internal commitment by providers to ongoing self-assessment and quality improvement. However, an internal commitment is not sufficient. There is also a need for external entities to monitor general levels of quality, to identify areas in which improvements are needed, and to use appropriate means to get providers to change their behavior when required.

The case for continuous quality improvement has been made most eloquently by Donald Berwick of the Harvard Community Health Plan:

"Real improvement in quality depends . . . on understanding and revising the production processes on the basis of data about the processes themselves. . . . When one is clear and constant in one's purpose, when fear does not control the atmosphere (and thus the data), when learning is guided by accurate information and sound rules of inference, when suppliers of services remain in dialogue with those who depend on them, and when the hearts and talents of all workers are enlisted in the pursuit of better ways, the potential for improvement in quality is nearly boundless."¹

¹D. Berwick, "Sounding Board: Continuous Improvement as an Ideal In Health Care," New England Journal of Medicine, 320:1 (1989), 54.

However, Berwick also acknowledges the need for external monitoring, noting that "politically, at least, it is absolutely necessary for regulators to continue to ferret out the truly avaricious and dangerously incompetent."²

We also believe that external reviewers have legitimate and necessary functions to serve. The primary function is overall surveillance and monitoring of the health care system. In addition, a number of developmental and technical assistance roles are essential to establishing a comprehensive, national quality assurance strategy. They include assisting providers in the development of quality measurement tools, aggregating data on quality centrally to help providers learn from each other, providing technical support and training in the principles of quality improvement, encouraging and funding studies designed to expand the knowledge base on medical care effectiveness, and specifying relevant quality review criteria.

In order to establish and maintain an appropriate balance, both internal and external quality assurance workers must do their part. External reviewers can adopt attitudes and strategies that acknowledge and encourage the efforts of individual providers to ensure that their patients receive quality care. For example, an approach that focuses on developing information on variations among providers in treating particular conditions and working with providers to reduce that variation may be more acceptable and effective than labeling aberrant providers as "bad" and demanding that they change. Providers who demonstrate that their behavior consistently conforms to established quality standards might be reviewed less frequently or less intensively. Similarly, such providers might be given an advantage as purchasers develop contracts with selected provider groups. On the other side, it is the responsibility of providers to be attentive to new information on health care effectiveness as it becomes available and to develop and maintain programs that demonstrably lead to continuing improvements in quality.

²Berwick, p. 54.

Elements of a Comprehensive National Strategy

Practice Guidelines and Standards

We believe that national, publicly available practice guidelines and standards are an essential element of a comprehensive quality assurance system. We use the term "practice guidelines" to refer to guidelines that assist in determining how diseases, disorders, and other health conditions can most effectively be prevented, diagnosed, treated, and clinically managed. Nevertheless, the circumstances of individual patients may justify deviations from practice guidelines. The term "standards" is used to refer to a variety of either professionally or statistically derived standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the quality of health care.

The difficulties inherent in developing such practice guidelines and standards should not be understated. For example, it is important to base guidelines and standards on sound scientific evidence about the effectiveness of medical care whenever possible and to allow more flexibility and variation in medical practice when uncertainty exists. The development of practice guidelines and standards for some conditions and procedures is feasible.

However, there is general agreement that the knowledge base on the efficacy and effectiveness of many aspects of medical care is weak or nonexistent. Here, the development of guidelines and standards will require additional information on medical care effectiveness. A mechanism for the development and updating of practice guidelines and standards is needed. Other difficulties that will have to be resolved include specifying appropriate methods for developing and reviewing guidelines and standards, setting priorities for which guidelines and criteria to develop and when to update and revise existing guidelines and standards, and pilot-testing, evaluating, and disseminating the guidelines and standards.

In addition, simply developing the guidelines and making them public will not, by itself, ensure quality. For example, the New England Journal

of Medicine recently published a study about the effect of cesarean section guidelines on the use of cesarean sections.³ Despite widespread knowledge and endorsement of the guidelines by the obstetricians in Ontario, Canada, and a belief that they had reduced their use of cesarean sections, actual rates of cesarean section changed very little after the introduction of the guidelines. However, the Maine Medical Assessment Foundation has had some notable successes in changing physicians' practice patterns with a combination of education and feedback about how their practice patterns compare to those of their peers.

More research and experimentation is needed on the effectiveness of alternative strategies for making guidelines available to physicians and encouraging them to accept them and change their behavior as needed. And the guidelines and standards will have to be incorporated into effective internal and external programs for assessing and assuring quality of care.

Finally, there has been considerable discussion about the potential for the use of practice guidelines to reduce the provision of inappropriate or unnecessary care, thereby reducing health care expenditures and possibly saving sufficient money to pay for an expansion of coverage to persons currently uninsured. This is an appealing concept. Partial estimates of potential savings range from \$139 million in Medicare Part B expenditures if guidelines were used for a set of just eight specific procedures to about \$808 million if practice guidelines for the same procedures were used by all purchasers of care. If, in addition to reductions in the inappropriate use of services, one could make reductions in the overall intensity of services, average annual savings could be \$22 billion.⁴

However, some of the estimates fail to account for the potential cost of alternative treatments that might be provided in place of procedures found to be inappropriate and the likelihood that a program intended to reduce inappropriate care would never be fully successful. Some fail to consider the possibility that the use of some practice guidelines might actually increase expenditures over the long run by increasing the number of services and procedures that are not now provided as often

³S.L. Lomas, et al., "Do Practice Guidelines Guide Practice?" *New England Journal of Medicine*, 321 (1989), pp. 1306-1311.

⁴These particular estimates were published in a technical appendix to National Leadership Commission on Health Care, *For the Health of a Nation* (Ann Arbor, Mich.: Health Administration Press, 1989).

as they should be. For these and other reasons, it is unclear whether potential cost savings might be obtained by using practice guidelines.

Despite the difficulties involved in developing and using national guidelines and standards, the need for them has been recognized. The Council of Medical Specialty Societies, the American Medical Association, and other provider organizations have publicly endorsed the need for the medical profession to step forward and take the lead in developing guidelines and standards. The National Leadership Commission, the Physician Payment Review Commission, the Institute of Medicine, and others have recommended that effectiveness research and guideline development be made a top priority. The Congress has created the Agency for Health Care Policy and Research within the Public Health Service

"to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services." (Public Law No. 101-229, sec. 6(a))

The Agency is to accomplish this purpose by conducting and supporting a wide range of activities including research, evaluations, demonstrations, education and training, data and data base development, information dissemination, and development of practice guidelines and standards.

An Enhanced Data System

We believe that a data base that contains at least a set of minimum data elements collected on each health care encounter regardless of purchaser or setting and that integrates those data for analysis is an important element of a comprehensive quality assurance system. The data should include information not only on the medical care provided during the encounter but also on any judgments about quality. An enhanced data base would enable monitoring the quality of care provided to individual patients across health care settings and providers. For example, evaluating the outcome of a surgical intervention requires knowing what happened to the patient after he or she left the hospital. An enhanced data base would also allow for the profiling of individual provider practice patterns based on care paid for by all purchasers rather than a single purchaser. Currently, these types of analyses are often not possible. In addition, health and functional status information on samples of the population would be needed in order to track changes in the

health of the population over time and identify variation in health outcomes and functional status among population groups or geographical areas. This would be useful in monitoring the performance of the health system as a whole and setting national health priorities.

For hospital care, it would be possible to build upon existing claims formats and fairly uniform hospital discharge data across purchasers. However, for other settings, there is very little uniformity across purchasers. An area of particular concern is the lack of experience with obtaining detailed information from ambulatory care settings and particularly from physicians' offices. For Medicare and some private insurers, diagnostic data are now included on claim forms used for ambulatory care. This will be useful but still quite minimal for quality assessment purposes. Significant attention will have to be devoted to defining an appropriate set of minimum elements for this type of health care encounter and to ensuring that the information provided is reliable and valid. The recent revision to the 1981 National Ambulatory Medical Care Minimum Data Set by the National Committee on Vital and Health Statistics provides a start toward specifying such a set of data elements.

Even with agreement on the appropriate data elements, the implementation of an integrated data system will not be simple. The resources required for collecting, processing, and maintaining this data base will be substantial and include both human resources and computer hardware and software. The integration of data across settings, providers, and purchasers will require the use of unique, common identifiers for providers and purchasers as well as for patients. The data coming into the system must be checked regularly to ensure their accuracy. The data will have to be organized so that all encounters for an individual patient, as well as all services provided by a particular provider, can be easily collated and analyzed. The system must also be flexible enough to accommodate the inevitable changes and improvements in data and quality assessment methods that will come with time. Safeguards for privacy and confidentiality will also need to be addressed.

An Improved System of Local Review

Our reviews of the literature as well as the results of some quality review programs leave little doubt that significant numbers of patients are currently receiving inappropriate or poor-quality care. For example, in past studies, we have cited estimates of rates of inappropriate use of surgical procedures ranging from 14 to 32 percent as well as rates of

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inappropriate hospital admissions ranging from 7 to 19 percent.⁵ In addition, our evaluations of current quality assurance programs suggest that those programs are not identifying significant proportions of cases with potential quality problems. For example, SuperPRO regularly reviews a random sample of Medicare cases previously reviewed by PROs and typically questions the appropriateness of hospital admission in almost six times as many cases as the PROs.⁶ Similarly, our review of the initial screening of cases in military hospitals for occurrences indicating potentially substandard care found that many such occurrences were missed in the initial screening process.⁷

Despite the importance of continuous quality improvement strategies in the long run, our past work has shown that improvements in external quality assurance mechanisms are needed in order to achieve the goal of appropriate, high-quality medical care for all Americans. We believe that there are a number of key components for improving the conduct of quality assurance within the framework of a comprehensive, national strategy. First, the quality assurance activities need to be conducted by local review entities that are held accountable for identifying instances of poor quality and improving overall patterns of care within their geographical area. Second, the local review entities should have available a uniform set of methods for reviewing care (including practice guidelines and standards), developing and implementing interventions and reporting information on the results of reviews and interventions. Finally, a national organization is needed to develop the national guidelines and review methods and to coordinate and oversee the activities of the local review entities.

By local review entities we mean organizations that are close enough to the local health care community that appropriate recognition of the unique circumstances of the community can be made and that the type of balanced quality assurance system we advocated earlier can be fostered and maintained. The state-level PRO program is one organizational model that approximates this goal. The individual PROs are charged with ensuring that the care provided to Medicare beneficiaries is appropriate and of high quality and, at the same time, with maintaining a positive, cooperative relationship with the provider community.

⁵U. S. General Accounting Office, Medicare: Improvements Needed in the Identification of Inappropriate Hospital Care, GAO/PEMD-90-7 (Washington, D.C.: December 20, 1989), pp. 3-4.

⁶U. S. General Accounting Office, Medicare, p. 3.

⁷U. S. General Accounting Office, DOD Health Care: Occurrence Screen Program Undergoing Changes but Weaknesses Still Exist, GAO/HRD-89-36 (Washington, D.C.: January 5, 1989).

Greater uniformity and effectiveness in review methods, intervention approaches, and reporting of results will be necessary in order to ensure that all patients are receiving an equally high level of quality. However, moving toward greater uniformity is not meant to imply that all reviews must be identical. Some flexibility is needed to tailor review methods and interventions to specific situations. For example, generally speaking, reviewing the appropriateness of a hospital length of stay would be reasonable. However, since the Medicare Prospective Payment System reimburses hospitals a set amount regardless of the length of stay, the incentive for hospitals is to release patients earlier rather than later. Therefore, the review of the appropriateness of a hospital discharge under Medicare generally focuses on the possibility that premature discharge has occurred rather than on inappropriate days at the end of the stay.

A variety of existing methods of quality assessment could serve as the core of the common review approaches. Reviews could be done prior to care being received (prospective review) that typically focus on the need for particular procedures, the appropriateness of the proposed setting (often the hospital), and the proposed length of stay. The limited information available suggests that these reviews are cost-effective.

Reviews could be done while the care is being delivered (concurrent review) and would typically focus on the need for continued care but might also address a lack of expected progress or improvement. This type of review tends to be expensive and is often limited to potentially high-cost cases.

Reviews could be done after the care is completed (retrospective reviews) that examine the process and outcomes of care based on information contained in the medical record or on the claims form. Reviews based on the medical records are relatively expensive but can address a wide range of appropriateness and quality concerns, including both overuse and underuse.

Reviews could be done of aggregate data from either claims or medical records (profiling; small area variation analysis) that focus on identifying providers who differ in one way or another from their peers in their process or outcome of care. These could be used to target both prospective and retrospective reviews.

Reviews could be done of prescription drug use, prospectively or retrospectively, that focus on ensuring appropriate use and limiting adverse

reactions and also allow the targeting of educational and other interventions for both patients and providers.

Similarly, a number of intervention approaches that have been tried could serve as the basis for developing a uniform set of interventions for use by local review entities.

One approach is that of undertaking educational interventions aimed at providing the medical community with information on the appropriate uses and costs of various medical services. The evidence on the effectiveness of this approach in changing provider behavior is mixed.

Another is to provide feedback of review results to providers, either on individual cases or on aggregate practice patterns. While generally viewed as more effective than simple educational interventions, its usefulness has been limited by the unavailability of comprehensive data across purchasers and settings.

Yet another approach consists of restrictions on providers' use of particular services (such as the total number of laboratory tests) or on their practice (such as hospital or operating room privileges). Restrictions have sometimes been met with resistance and often change behavior only as long as they remain in place.

One more approach is to offer incentives (such as increased reimbursement, more patients, reduced administrative requirements) for providers to conform to particular standards of medical practice. These are being increasingly used, particularly in managed care organizations such as preferred provider organizations and health maintenance organizations.

Last, monetary sanctions can be imposed or providers can be excluded from the program (as in the Medicare program) if they provide poor-quality care and are unwilling or unable to change their practice patterns.

Additional development, experimentation, and evaluation of both assessment and intervention techniques will be needed in order to create an effective, comprehensive, national strategy.

Finally, even though some flexibility in the implementation of reviews and interventions is necessary, a common set of reporting requirements, and particularly reporting categories, will be needed in order to oversee

and evaluate the quality assurance activities at a national level. One of the greatest weaknesses of the current system of quality assurance is that there is no simple way to compare information on quality of care from one program to another or to monitor changes in levels of quality over time. This is another area in which developmental work is needed.

A National Organizational Focus

We believe a national organizational focus is required to accomplish the many developmental, implementation, and evaluation tasks needed to set up and operate a comprehensive, national system of quality assurance. Some of the developmental tasks have been alluded to above—supporting research on the effectiveness of medical care and developing improved quality assessment and assurance techniques. Others include developing practice guidelines and standards, uniform reporting requirements for both medical data and data on the results of quality reviews, and methods of changing provider behavior, including approaches for fostering internal quality assurance activities. Implementation will require the development and oversight of local review organizations that have the necessary tools and skills in data integration and analysis, quality assessment, and quality assurance. Finally, the national organization will also require considerable expertise in data analysis, evaluation, and management in order to integrate the information coming from the various local review entities into a national picture of health care quality, to evaluate the performance of the local review entities, and to identify areas in which greater attention to quality is needed.

The Role of Provider Accreditation and Certification

Most of the discussion of quality assurance to this point pertains to the review of care provided to individual patients. However, it is also important to review the credentials, facilities, staff, and administrative procedures of health care providers (so-called “structural” quality assurance) to determine a provider’s capability or potential for providing high quality care. While such review cannot ensure that quality care is actually provided, it is important for ensuring that at least the necessary elements for providing quality care exist and that providers without those elements are not allowed to participate.

Established accreditation or certification programs exist for hospitals, nursing homes, and many ambulatory care settings. However, one setting in which little review of this type occurs is the individual physician’s office. We believe that such review may be particularly important for physicians who do not have hospital admitting privileges and who are not part of a larger medical network through which their care might

be scrutinized. For selected physicians in this category, on-site visits might be warranted to ensure that medical records are legible, integrated, and filed; that X-ray and laboratory equipment is properly calibrated, maintained, and used; and that the process of care (as revealed through a review of patients' records) is appropriate and high in quality.

The Importance of Consumer Education

Expanding access to care may bring some patients into the traditional health care system for the first time. They will need assistance in learning to access the system appropriately, select primary care physicians, and understand the importance of an ongoing relationship with an "accountable" provider. Providers will need assistance in working with these new patients and helping them to use the system wisely. All consumers will need assistance in using the increasingly available information on the appropriateness and quality of care to make prudent choices among providers.

Conclusion

We believe that a comprehensive national quality assurance strategy is needed in order to ensure that all Americans receive high-quality medical care. A comprehensive national strategy is important for several reasons: (1) to ensure that the treatment of individuals does not depend on how the care is financed; (2) to be able to examine the contents, appropriateness, and outcomes of care, regardless of when and where the care was provided or who paid for it; and (3) to meet the legitimate needs for information on quality of the many different actors in the health care system.

We see four essential elements of a comprehensive national strategy:

- national practice guidelines and standards of care,
- enhanced data to support quality assurance activities,
- improved approaches to quality assessment and assurance at the local level, and
- a national focus for developing, implementing, and monitoring a national system.

We believe that the basic elements necessary to move toward a comprehensive national strategy currently exist. However, additional time and resources will be required to fully develop, implement, and evaluate the

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components that will make the system truly effective. The understanding and cooperation of health care providers, purchasers, consumers, and policymakers are also essential.

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Related GAO Reports

Medicare: Improvements Needed in the Identification of Inappropriate Hospital Care (GAO/PEMD-90-7, December 20, 1989).

Medicare: Assuring the Quality of Home Health Services (GAO/HRD-90-7, October 10, 1989).

VA Health Care: Improvements Needed in Procedures to Assure Physicians Are Qualified (GAO/HRD-89-77, August 22, 1989).

Health Care: Initiatives in Hospital Risk Management (GAO/HRD-89-79, July 18, 1989).

Prescription Drugs: Information on Selected Drug Utilization Review Systems (GAO/PEMD-89-18, May 24, 1989).

DOD Health Care: Occurrence Screen Program Undergoing Changes but Weaknesses Still Exist (GAO/HRD-89-36, January 5, 1989).

Medicare: An Assessment of HCFA's 1988 Hospital Mortality Analyses (GAO/PEMD-89-11BR, December 13, 1988).

Medicare PROs: Extreme Variation in Organizational Structure and Activities (GAO/PEMD-89-7FS, November 8, 1988).

VA Hospital Care: A Comparison of VA and HCFA Methods for Analyzing Patient Outcomes (GAO/PEMD-89-29, June 30, 1988).

Medicare: Improved Patient Outcome Analyses Could Enhance Quality Assessment (GAO/PEMD-88-23, June 27, 1988).

Medicare: Improving Quality of Care Assessment and Assurance (GAO/PEMD-88-10, May 2, 1988).

VA Health Care: Assuring Quality of Care for Veterans in Community and State Nursing Homes (GAO/HRD-88-18, November 12, 1987).

Medicare: Preliminary Strategies for Assessing Quality of Care (GAO/PEMD-87-15BR, July 10, 1987).

Medicare: Reviews of Quality of Care at Participating Hospitals (GAO/HRD-86-139, September 15, 1986).